Can We Improve the Assessment of Discharge Readiness?

A Comparative Study of Observational and Objective Measures of Depth of Sedation in Children

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Background: Current recommended discharge criteria might not be rigorous enough to detect residual sedation. This study evaluated the use of the Bispectral Index (BIS® monitor), the University of Michigan Sedation Scale (UMSS; *i.e.*, 0–4 observational scale), and a Modified Maintenance of Wakefulness Test (MMWT; visual observation of the time the child is able to stay awake) in assessing return to baseline status.

Methods: Twenty-nine children sedated for echocardiographic examination were studied. Nurses administered sedatives and monitored and discharged children according to institutional guidelines. Children were monitored with the BIS® throughout the study. Trained observers assigned UMSS scores every 10–15 min until revised discharge criteria were met (*i.e.*, UMSS score of 0 or 1, MMWT duration ≥ 20 min). The MMWT value was recorded at each observation following the procedure. Subsequently, blinded observers recorded average BIS values for the 5 min before each UMSS observation.

Results: There were moderate correlations between the BIS, MMWT, and UMSS scores ($r = 0.68$–0.78; $P < 0.01$). Revised criteria correctly identified children who were awake and alert (BIS value ≥ 90) in 88% of the cases. Only 55% of the children had returned to baseline BIS values when discharged by the nurse, compared with 92% when revised criteria were met ($P < 0.05$). It took longer to meet revised criteria compared with standard criteria (75.3 ± 76.2 min *vs.* 16.4 ± 13.1 min; $P = 0.001$).

Conclusions: The incorporation of specific, objective discharge criteria (*i.e.*, UMSS score of 0 or 1, MMWT duration ≥ 20 min) may ensure a status closer to baseline (BIS value ≥ 90) compared with nursing judgment using standard criteria. However, such assurance may delay the discharge of sedated children.

SEDATION guidelines from the American Academy of Pediatrics[1] and the American Society of Anesthesiolo-

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gists[2] stipulate the need for frequent assessment of depth of sedation throughout a procedure and the return to baseline level of alertness before discharge. More specifically, recommended criteria state that the "presedation level of responsiveness or a level as close as possible to the normal level for that individual should be achieved [before discharge]."[1] However, current methods to assess return to baseline and discharge readiness are at the discretion of the sedation care provider and may be subject to observer bias. Recent data suggest that these general guidelines may not be rigorous enough to ensure the safety of sedated children after discharge.[3-5] Studies have revealed several sedation-related adverse events, including death, which were related to premature discharge of the child.[3-5] Some of these cases occurred despite the presence of sedation guidelines with the language described above.[4,5] This suggests that discharge criteria either were not adhered to or perhaps were not rigorous enough to detect residual sedation.

The method to assess sedation depth in the clinical setting typically involves the use of an observational scoring system. The University of Michigan Sedation Scale (UMSS) is one such tool that scores the level of alertness from 0 (*i.e.*, awake and alert) to 4 (*i.e.*, unarousable) (table 1).[6] A recent study in young children supported the psychometric properties of the UMSS, including interrater and test–retest reliability and criterion and construct validity.[6] However, these data also suggested the tendency of the bedside caregiver to underestimate the depth of sedation compared with nurses viewing videotapes, blinded to the sedation regimen. This tendency may have led to premature discharge in a number of cases, despite the presence of institutional sedation guidelines.

The only truly objective and clinically feasible method to assess depth of sedation is the Bispectral Index (BIS® monitor; Aspect Medical Systems, Inc., Newton, MA), a derivative of the processed electroencephalogram that yields a number between 0 (no electroencephalographic activity) and 100 (fully awake). Although the BIS has not been used to assess discharge readiness, it has been tested in sedated and anesthetized adults and children in the operating room, intensive care unit, and during short episodes of sedation for medical procedures.[7-17] BIS values have been shown to correlate inversely with hypnotic drug effect in adults and children older than 6

Table 1. University of Michigan Sedation Scale

Score	Descriptors
0	Awake and alert
1	Minimally sedated: tired/sleepy, appropriate response to verbal conversation and/or sound
2	Moderately sedated: somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command
3	Deeply sedated: deep sleep, arousable only with significant physical stimulation
4	Unarousable

Table 2. Standard Institutional Discharge Criteria*

Vital signs, oxygen saturation, and level of consciousness are stable compared to the presedation baseline state
The ambulatory patient must be able to maintain a patent airway independently, manage oral secretions or demonstrate the ability to swallow, demonstrate an active gag reflex if appropriate, and have the ability to move and ambulate safely or consistent with preprocedure status.

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months,[7,9,12,18] making it a useful criterion for assessing sedation depth. The Maintenance of Wakefulness Test (MWT) has been used to assess daytime somnolence in patients with sleep disorders.[19,20] It is a polysomnographic measure of the time taken for a patient to fall asleep when instructed to stay awake in a quiet, darkened room. This test has not been used to assess residual sedation, and in addition, the use of polysomnographic techniques may be impractical in the daily clinical setting. However, a similar measure of duration of wakefulness may provide a sensitive indicator of the patient's recovery after sedation.

The purposes of this study were (1) to evaluate the validity of the UMSS and a modified MWT (MMWT) in assessing recovery to baseline after sedation and (2) to determine whether the incorporation of specific discharge criteria based on UMSS scores and MMWT duration would ensure a level of alertness closer to baseline. We hypothesized that the child's level of alertness would be closer to baseline when revised, specific criteria, compared with standard global discharge criteria, were applied.

Materials and Methods

With approval from the University of Michigan institutional review board (Ann Arbor, Michigan) and parental informed consent, children with congenital heart disease who required sedation for echocardiographic examination were studied. Children who were scheduled to be discharged to an unmonitored setting (*i.e.*, home or general care unit) after sedation were included. Children were excluded if they needed prolonged or ongoing sedation or were critically ill. The choice of sedative agents was at the discretion of the cardiologist responsible for the care of the child. Sedatives were administered and children were monitored in accordance with institutional guidelines by one of two pediatric nurses, each with several years of experience in the care of sedated children. In accordance with routine practice, children were discharged from the monitored setting at the discretion of the sedation nurse applying institutional discharge criteria (table 2), based on her own

observations and UMSS scores, not those of the observers as outlined below.

Definitions

For the purpose of this study, the MWT was modified to provide a new, clinically useful technique to measure the child's ability to stay awake *versus* excessive somnolence. This modified tool, the MMWT, is a simple visual observation of the time that the child is able to maintain wakefulness in a soporific environment (*i.e.*, dim, quiet room). Specifically, the MMWT duration was measured from the time the child was awakened (to determine the UMSS score) through the time the child seemed to fall asleep (*i.e.*, eyes closed, relaxed facial muscles, deepened regular respiratory pattern). Children were considered awake if they were able to open their eyes and respond appropriately to parents or caregivers. Because the MWT sleep latency in normal adults has been previously reported as 17.9 ± 4.4 min,[19] we chose to monitor children until they had an MMWT of at least 20 min. For the purpose of this study, the standard discharge criteria as described in table 2 were revised to include specific criteria for assessment of level of consciousness. These criteria included a UMSS score of 0 or 1 and an MMWT duration of at least 20 min.

Procedure

The BIS® sensor was applied to the forehead, in accordance with manufacturer instructions, before sedation for continuous recording throughout the study. The monitor used for this study was the A-2000 BIS® (Aspect Medical Systems, Inc.). The monitor was positioned out of view of direct patient care, so as not to influence other observations or care. A trained observer assigned UMSS scores at baseline, every 10 min until the child was discharged from the monitored setting, and every 15 min thereafter until revised discharge criteria were met. The same sequence of stimulation was applied to determine the appropriate UMSS score: verbal stimulation, and if no response, light touch or stroking, followed by deeper stimulation such as tickling under the arm or sitting the child up—being sure to support the head while doing so. To avoid waking the child and potentially aborting the procedure, UMSS scores were not assigned during the procedure when children could not be stimulated. The MMWT durations were recorded by the same trained
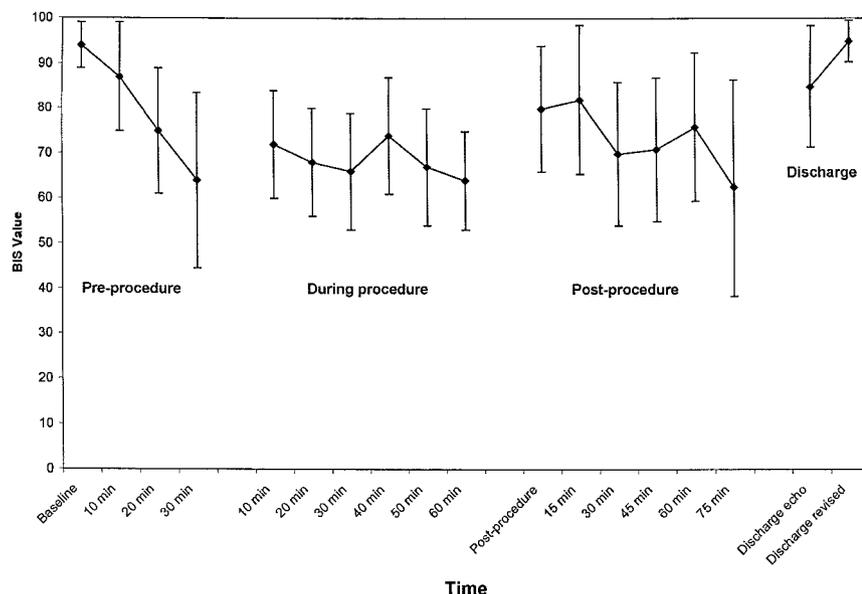
Fig. 1. Bispectral Index (BIS) values over the course of sedation for the entire sample. The sample size for each time point may be variable because the start of the procedure, the duration of the procedure, and recovery varied for each child. Data are not presented for time points that included less than 10 children. Echo = echocardiogram.

observer at each observation following the procedure until revised discharge criteria were met. The exact time of each observation was recorded. Using these times, BIS recordings were later reviewed by a separate observer blinded to the UMSS scores and the sedation course to determine BIS values at each observation time. This BIS value was derived from the average over the 5-min period immediately before stimulation of the child for assignment of the UMSS. Data with a signal quality index less than 50 were not used for this averaging. The following data were also recorded: patient demographics, information regarding the child's routine napping habits, sedative agents, dosages and time of administration, procedure start/end times, time of discharge from monitored setting, and time until revised discharge criteria were met.

Statistics

The Pearson R and Spearman ρ correlation coefficients were used to evaluate the relations between UMSS scores, MMWT durations, and BIS values. An analysis of variance with repeated measures was used to examine changes in BIS values across different UMSS scores. Pairwise comparisons with Bonferroni corrections were used for *post hoc* analysis. Kappa statistics were used to evaluate exact agreement between UMSS assigned by the bedside nurse and observer. Kappa values of 0.4 or greater were considered to represent acceptable agreement. Unpaired *t* tests were used to compare parametric data such as BIS values and times to discharge. *P* values of less than 0.05 were accepted as statistically significant.

The sample size was based on the number of children needed to demonstrate a clinically significant difference in return to baseline using standard criteria *versus* revised criteria. Based on our previous study, only 50% of

children had returned to baseline activity after discharge as judged by a parent.[4] We estimated that the application of rigorous criteria should ensure that at least 90% of children would return to a baseline level of alertness at discharge. To demonstrate this difference, 19 children would need to be studied at discharge using standard criteria and when meeting revised criteria ($\alpha = 0.05$; $\beta = 0.2$). In addition, to ensure enough observations to demonstrate significant and moderate correlations (*i.e.*, r = 0.5) between the BIS, UMSS, and MMWT variables, at least 38 observations would be required ($\alpha = 0.05$; $\beta = 0.1$).

Results

Thirty-seven children were recruited for this study; however, in eight cases, the BIS sensor did not adhere. Therefore, data from 29 children (American Society of Anesthesiologists physical status class III; aged 1 ± 0.6 yr; 76% male; 48% cyanotic) are presented. Twenty-seven children (93%) received chloral hydrate (52–79 mg/kg; 65.9 ± 7.3 mg/kg), and two (7%) received midazolam/diphenhydramine (0.1/0.8 and 0.5/0.9 mg/kg, respectively). These regimens facilitated successful completion of the echocardiographic examination in all cases.

Figure 1 presents the BIS values over the course of sedation for the entire sample. For illustrative purposes, the BIS values, UMSS scores, and MMWT times over the course of sedation in one child are presented in figure 2. There were moderate and significant correlations between UMSS scores, MMWT durations, and BIS values for all children (table 3), supporting the criterion validity of these measures. In addition, there were significant correlations and excellent measures of exact agreement between UMSS scores that were assigned independently

Fig. 2. Illustration of the entire course of sedation in one child in relation to Bispectral Index (BIS) range guidelines from Aspect Medical Systems, Inc. CH = chloral hydrate; MMWT = Modified Maintenance of Wakefulness Test; UMSS = University of Michigan Sedation Scale.
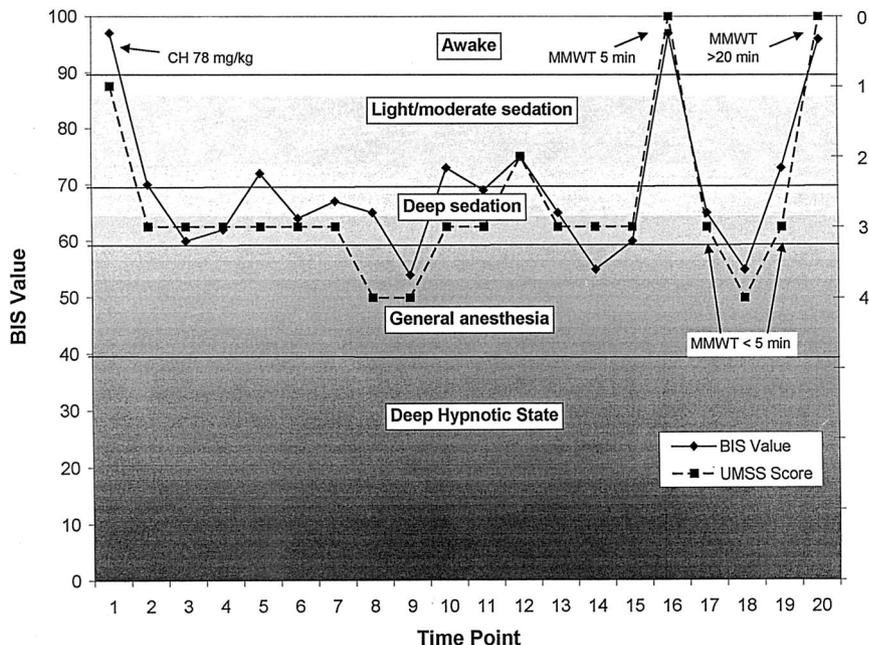
by the sedation nurse and observer. Figure 3 shows the relation between BIS values and UMSS scores. Analysis of variance with repeated measures showed significant differences in BIS values across all UMSS scores ($P < 0.001$). In 86% of the cases in which UMSS scores were 0 or 1, children were able to maintain wakefulness for more than 20 min. In contrast, when UMSS scores were 2 or 3, only 7% could do so. Notably, 61% of the children with UMSS scores of 2 or 3 could not stay awake for even 5 min.

The sensitivity and specificity of the UMSS and MMWT to detect discharge readiness were evaluated by determining the proportion of values that correctly identified children who were awake/alert according to BIS values (*i.e.*, BIS value $\geq$ 90) and those who were sedated (*i.e.*, BIS value $<$ 90), respectively. The positive predictive value of each measure (*i.e.*, UMSS score of 0 or 1 and MMWT duration $\geq$ 20 min), as well as of the two measures combined, was evaluated by calculating the proportion of patients with a BIS value of 90 or greater who were correctly identified by each measure individually and when combined. These data are presented in table 4. Combined criteria correctly identified children who

were awake and alert by BIS in 88% of the cases. In the three children who met the revised criteria but had BIS values of less than 90, these values were 84.5, 85, and 87, suggesting a light level of residual sedation.

Of the 29 children included in this study, 5 removed their BIS sensors on awakening. Therefore, discharge data were evaluated for 24 children. Table 5 presents comparative data related to the children's status when discharged by the sedation nurse using standard criteria *versus* when they met revised criteria. BIS values were significantly lower when children were discharged by the sedation nurse compared with when they met revised discharge criteria. In seven children, BIS values

Table 3. Correlations between Observational (UMSS) and Objective Measures of Sedation Depth

Variables (No.)	r^*	r^2
UMSS–BIS (223)	-0.676	-0.457
UMSS (observer)–MMWT (61)	-0.765	-0.585
BIS–MMWT (54)	0.694	0.482
UMSS (observer)–UMSS (RN) (77)†	0.793	0.629
UMSS (RN)–MMWT (observer) (69)	-0.613	-0.375

* All correlations significant with *P* values less than 0.01.   † $\kappa = 0.79$.

BIS = Bispectral Index; MMWT = Modified Maintenance of Wakefulness Test; RN = registered nurse; UMSS = University of Michigan Sedation Scale.
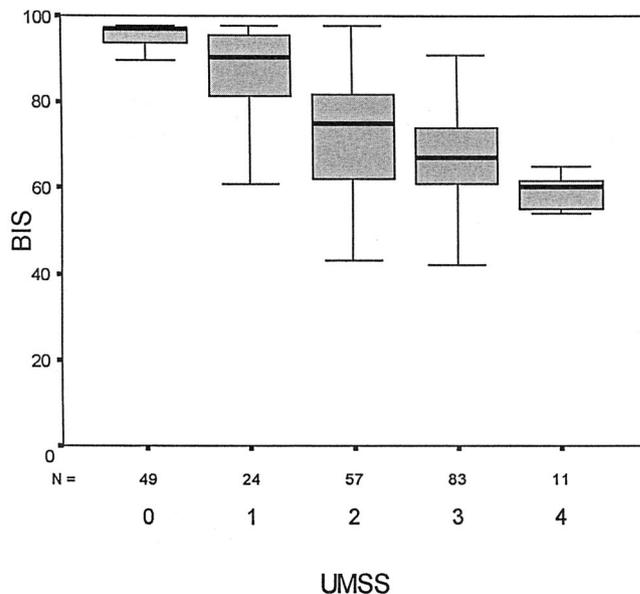

Fig. 3. The relation between Bispectral Index (BIS) values and University of Michigan Sedation Scale (UMSS) score.

Table 4. Sensitivity, Specificity, and Predictive Values of UMSS and MMWT*

	UMSS 0 or 1	MMWT ≥ 20 min	Both Criteria
Sensitivity (%)	89	77	74
Specificity (%)	87	89	88
Positive predictive value (%)	70	89	88

* Evaluated relative to Bispectral Index values of 90 or greater (awake/alert) *vs.* less than 90 (sedated).

MMWT = Modified Maintenance of Wakefulness Test; UMSS = University of Michigan Sedation Scale.

were 76 or less (*i.e.*, moderately to deeply sedated) when, in the nurse's opinion, they met standard criteria. In contrast, all of the children had a BIS value of 81 or higher when they met revised criteria. Only 55% of the children had returned to their baseline BIS value (within 10%) when discharged by the sedation nurse, compared with 92% when revised criteria were met ($P < 0.05$). Although all children were able to maintain wakefulness for 20 min to meet the revised criteria, 73% of the children could not stay awake for even 10 min when discharged by the sedation nurse. Not unexpectedly, discharge times were significantly longer when the revised criteria were applied (table 5). Interestingly, the duration from sedative administration to meeting revised discharge criteria was no different for children whose routine nap times overlapped with the sedation experience compared with those who did not routinely nap during this period (138 ± 59 *vs.* 142 ± 52 min, respectively).

Three children in this sample experienced a paradoxical reaction; two before the echocardiographic examination and one immediately afterward. Nine children (31%) experienced oxygen desaturation. Five of these (17%) had a 5–10% reduction in oxygen saturation measured by pulse oximetry (Sp_{O_2}), whereas four (14%) had

Table 5. Comparison of BIS Values and UMSS Scores at Discharge (n = 24)

	Standard Criteria	Revised Criteria
BIS value at discharge	86 ± 18	95 ± 5*
Change from baseline	-7.1 ± 14.6	1.5 ± 5.6
UMSS score, No. (%)		
0—Awake/alert	10 (42%)	19 (79%)
1—Awake but drowsy	6 (25%)	5 (21%)
2—Awakens with verbal/light stimulation	4 (17%)	0
3—Awakens with vigorous stimulation	4 (17%)	0
Change from baseline	-1.0 ± 1.1	-0.13 ± 0.5*
Minutes from procedure end to discharge	16.4 ± 13.1	75.3 ± 76.2*
Minutes from sedative administration to discharge	88.2 ± 18.7	145.8 ± 78.1*

* $P \leq 0.007$ compared to standard criteria.

BIS = Bispectral Index; UMSS = University of Michigan Sedation Scale.

a reduction greater than 10%. One of these latter events occurred after the child was discharged from the monitored setting. In seven of these nine children, BIS values ranged between 47 and 73 during the desaturation episodes. These adverse events resolved without intervention or long-term sequelae.

Discussion

Previous investigators have emphasized the importance of implementation of and adherence to institutional guidelines to minimize sedation risks.[3–5,21,22] However, recent studies suggest that premature discharge to an unmonitored setting remains the weakest link in the care of sedated children.[3,4] Findings from our study suggest that the incorporation of specific, objective criteria may ensure a status closer to baseline at discharge compared with when nursing judgment using standard institutional criteria is applied. However, such assurance may impose a longer stay for children.

Similar to ambulatory surgery units, busy diagnostic and procedure areas demand rapid patient turnover to maintain efficient use of resources. The literature related to ambulatory surgery has balanced efficiency and patient safety issues by emphasizing the use of short-acting agents and the incorporation of specific scoring systems for the assessment of discharge readiness.[23–26] The safe discharge of ambulatory surgery patients with application of scoring systems has been well documented.[23,24] In contrast, the sedation literature emphasizes safety and monitoring during the procedure, but criteria for discharge readiness remain nebulous.[1,2] Reports of life-threatening and devastating adverse events after discharge[3,22] suggest that such subjective criteria must be replaced with objective and quantitative methods to provide a consistent way of assessing home readiness, particularly when agents with long half-lives are used.

The current method to assess discharge readiness after sedation includes the evaluation of level of alertness using observational scales such as the UMSS.[6] Although several observational tools have been validated in patients sedated for procedures,[6,27–29] limited data related to their use in assessing discharge readiness are available. The sensitivity, specificity, and positive predictive value of the UMSS in the current study demonstrate its ability to determine return to a baseline level of alertness in sedated children. Furthermore, moderate and significant correlations between the UMSS and the BIS support the criterion validity of this observational measure. Similar correlations have been previously reported between the BIS and the Sedation Agitation Scale in adults,[15–17] and the BIS and the COMFORT scale in children.[14] Taken together, these data suggest that when used objectively, observational methods are reliable in assessing depth of sedation. However, in the busy clinical setting, such

tools have been found to allow room for observer bias toward underestimating depth of sedation.[6] Therefore, additional objective measures may be required to assure the child's return to a baseline level of alertness.

Polysomnographic sleep studies may provide such an objective measure to assess residual somnolence after sedation. However, the use of these tests as described is impractical in the clinical setting. The Multiple Sleep Latency Test was found to be a more sensitive instrument for detecting residual anesthetic effects compared with psychomotor testing.[30] This test measures the time for the patient to fall asleep when instructed to do so in a soporific environment. The Multiple Sleep Latency Test is valid only if the patient is able to follow instructions, and results are therefore less useful in young children.[20] Another sleep study, the MWT, measures a different ability, *i.e.*, the ability to remain awake.[19] This test may be more relevant than the Multiple Sleep Latency Test when evaluating discharge readiness after sedation. Furthermore, because polysomnography is not feasible in routine clinical care, the visual observation of a child's ability to maintain wakefulness may provide a useful and quantitative technique to assess residual somnolence. It could be argued that the visual observation of the awake state *versus* the asleep state may be open to observer interpretation. However, such observation may provide the only practical and reasonably objective method to determine residual somnolence. We found that MMWT durations increased with BIS values over time as sedative effects wore off. In addition, MMWT durations correlated significantly with UMSS scores and had a reasonable positive predictive value toward the assessment of return to baseline level of alertness. These findings support the validity of the MMWT as a measure of recovery after sedation in children.

Children in this sample were closer to baseline when they met revised, combined criteria than when discharged by the echocardiography nurse. Not unexpectedly, it took significantly longer for children to meet these criteria, which in practice would have prolonged the required duration of stay in the monitored setting. The average time to discharge from the echocardiography suite was 90 min from sedative administration, compared with 145 min required to meet revised criteria. Given the pharmacokinetics of chloral hydrate in young children (*i.e.*, trichloroethanol peak effect 2.2 ± 1.2 h; half-life 9.7 ± 1.7 h),[31] this extended duration of stay seems reasonable. Previous investigators have reported serious adverse events after discharge that were attributed to premature discharge after administration of sedative agents with known long half-lives.[3] These investigators strongly recommended the need for rigorous discharge criteria and that children recover in a quiet, monitored setting even if they seem to be awake at the end of the procedure. Our data support this practice and further suggest that the use of combined criteria may

better assure the return to baseline, given the positive predictive value of 88% when both UMSS and MMWT criteria were applied. However, incorporation of such stringent criteria would likely necessitate an increase in resources or perhaps a step-down unit, similar to phase 2 recovery areas used for ambulatory surgery patients.

This study was intended to evaluate the child's return to baseline after sedation, with the goal of identifying objective, qualitative criteria for discharge. Although our data show that the application of specific criteria ensures a level of alertness closer to baseline, the relatively small sample size precludes any conclusions regarding improvements in the children's safety after discharge. Only one child in the study experienced a delayed oxygen desaturation after discharge from the monitored setting but before meeting revised criteria. Of interest is the finding that seven of nine children who experienced a decrease of greater than 5–10% in saturation had BIS values indicating deep sedation. Similarly, a recent study of 960 children showed an increase in complication rate with deeper levels of sedation.[21] Unfortunately, available data are insufficient to allow precise predictions about which children are at risk for resedation or delayed adverse events after discharge. Until further data become available, it would be prudent to consider all children who have received sedative agents with delayed peak effects and prolonged half-lives and those who are deeply sedated to be at risk.

One might argue that there is no definitive standard against which to assess discharge readiness based on level of alertness. Because clinical endpoints in children are frequently ambiguous, we chose to use the BIS as the definitive standard because it is, to date, the most objective clinical indicator of level of alertness. The validity of the BIS in children has been questioned because of reported variability between infants, toddlers, and older children[9,32]; however, several recent studies have found inverse relations between BIS and anesthetic concentrations in older infants (*i.e.*, > 6 months) and children similar to that reported in adults.[9,12,18] In our study, all children were aged older than 6 months. Furthermore, our data show that the BIS values decreased after sedative administration and increased toward baseline as sedative effects wore off. Therefore, these data provide further support of the construct validity of the BIS as a measure of depth of sedation in children aged older than 6 months.

These study findings are limited by several important issues. First, the sample size in this study was insufficient to allow evaluation of safety related to recovery and discharge criteria. Further study of these revised criteria in a much larger sample would be necessary to demonstrate improved safety. In addition, sedative agents such as ketamine may alter BIS values regardless of the depth of sedation.[33] Therefore, our data may not be extrapolated to children sedated with such agents. Last, al-

though UMSS scores correlated well with BIS values, the r^2 of 0.45 suggests that the variation between these two entities cannot be entirely explained by this association.

Ensuring a level of alertness close to baseline at discharge may enhance the safety of a sedated patient beyond the monitored setting. Findings from this study suggest that the use of specific and objective criteria are more likely to ensure the return to baseline compared with vague or ambiguous criteria. Our data further support the validity of the UMSS and MMWT in assessing return to the baseline level of alertness. Further study in a large sample of children is needed to determine whether application of these criteria reduces the incidence of adverse events after discharge.

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